OIPE
DEC 26 2002
PATENT & TRADEMARK OFFICE

#15
RD
1-8-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Joseph R. BYRUM *et al.*		Art Unit:	1631
Appln. No.:	09/521,640	Examiner:	Michael L. BORIN
Filed:	March 10, 2000	Atty. Docket:	16517.128/38-21(15750)D
For:	**Nucleic Acid Molecules and Other Molecules Associated with Plants**		

RECEIVED
JAN 0 2 2003
TECH CENTER 1600/2900

APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on September 23, 2002. The statutory fee of $320.00 for submitting this Brief should be charged to deposit account number 13-4125. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1-7 and 16-22 are pending. Claims 8-15 were canceled. Appellant appeals all of the rejections of claims 1-7 and 16-22.

12/30/2002 WABDELR1 00000092 134125 09521640
01 FC:1402 320.00 CH

4. Status of Amendments

Applicants have not filed any responses subsequent to Final Rejection in this case.

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule reciting a fragment of the sequence of a BAC (Bacterial Artificial Chromosomes) clone and its complement. The nucleic acid molecule was derived from a DNA collection prepared from soybean plants. Specification at page 12, lines 16-18. More particularly, the invention is directed to: a substantially purified nucleic acid molecule having the nucleic acid sequence of SEQ ID No. 2 or its complement or a fragment of either (claims 1, 4, 16, and 19); a nucleic acid molecule having the nucleic acid sequence of SEQ ID No. 2 or its complement or a fragment of either that contains a marker to be used in plant genetics (claims 2, 3, 17, and 18); a nucleic acid molecule having the nucleic acid sequence of SEQ ID No. 2 or its complement or a fragment of either that contains a bacterial ORI site, promoter, partial promoter region, or cis element to be used in plant transformation (claims 5, 6, 7, 20, 21, and 22).

6. Issues

The issues in this Appeal are:

(a) whether claims 1-7 and 16-22 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description;

(b) whether claims 1-7 and 16-22 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by either a specific and/or substantial utility or a well established utility; and

(c) whether claims 1-7 and 16-22 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility.

7. Grouping of Claims

Patentability of claims 1-7 and 16-22 is addressed together in Sections 8.A through 8.D below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Applicants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have proven that the claimed nucleic acid molecule, in their current form, provides at least one specific benefit to the public, *e.g.*, the ability to identify the presence or absence of a polymorphism in a population of soybean plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acids provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acid molecule for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Applicants have shown that the claimed nucleic acid molecule actually works for that and other utilities disclosed and described in the specification, and so both enablement rejections must be reversed. Applicants have proven that one skilled in the art is able to use the claimed nucleic acid molecule for at least one disclosed utility, namely use as a genetic marker for genetic mapping. The law clearly establishes that the enablement requirement is satisfied if at least one mode of making and using the invention is enabled. Because Applicants have proven that the claimed nucleic acid molecules work for the disclosed utility, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acid molecule that demonstrates Applicants' possession of the claimed invention. The genus of the claimed nucleic acid molecules, *i.e.*, nucleic acid molecules "comprising" and "consisting of" SEQ ID No. 2 have been described by the recitation of a "basic and novel" common structural feature – the nucleotide sequence of SEQ ID No. 2 – which distinguishes them from nucleic acid molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

B. The Specification Provides An Adequate Written Description of the Claimed Invention

The adequacy of the written description has been challenged by the Examiner because the nucleic acid molecule of claims 1-7 and 16-22 are allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 2 and at page 3. The bases for the Examiner's challenge are that (1) there is allegedly no adequate description "any single representative of the genus of fragments of 30-300 nucleotides of SEQ ID No. 2." (Final Action at page 3), and (2) that the use of the claim language "comprising" encompasses products that have not been described or disclosed (Final Action at Page 3).

(1) Applicants Have Described the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe" in the sense of

Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461 (Fed. Cir. 1989)

A related and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in the specification." *Ralston Purina Co. v. FarMar-Co,* 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA. 1981). Thus, simply because the claimed nucleic acid molecule may also include other nucleic acid molecules does not require that Applicants describe each and every one of these molecules. Further, "a description as filed is presumed to be adequate, unless and until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption." *Federal Register* 66(4): 1107, Written Description Guidelines (2001). In this regard, the Examiner is required to disclose an "express finding of fact which supports the lack of written description conclusion." *Id.* If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. For at least this reason, it is respectfully submitted that the present claims meet the written description provision under 35 U.S.C. § 112, first paragraph.

(2) The Specification Reflects Applicants' Possession of the Claimed Invention

Applicants have provided the nucleotide sequence required by the claims, *i.e.*, SEQ ID NO: 2, and have thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include fragments of 30-300 nucleotides of the recited sequence or the recited sequence joined with additional sequences does not mean that Applicants

were any less in possession of the claimed nucleic acid molecule.[1] A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, including the description at page 82, understand that the Applicants had possession of SEQ ID NO: 2 and 30-300 nucleotide fragments thereof, and therefore, the claimed invention.

The use of open claiming language (comprising) does not alter the fact that a skilled artisan would readily envision adequate written description support. The fact that additional nucleic acid sequences may be added to either end of the recited sequence is beside the point. It is well established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID No: 2). Fragments of the disclosed nucleotide sequence (SEQ ID No: 2) are readily envisioned by one of ordinary skill in the art upon reading the present specification, in particular as microarrays at (specification at page 58, lines 4-9) and as markers for plant breeding (specification at page 16, lines 14-16). Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence (SEQ ID No: 2) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[2] in particular as vectors

---

[1] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[2] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

comprising the claimed nucleic acid molecules (specification at page 59, lines 7-8) and as fusion molecules (specification at page 33, lines 10-13).

Accordingly, for at least the foregoing reasons, the rejection under 35 U.S.C. § 112, first paragraph, should be reversed.

C. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1-7 and 16-22 were erroneously rejected under 35 U.S.C. § 101 because the claimed invention was allegedly not supported by either a "specific and/or substantial utility" or a "well established utility." Final Action mailed June 24, 2002 ("Final Action") at page 4. According to the Final Action, the "Nucleic acid of SEQ ID No: 2 itself is not supported by a specific asserted utility because the uses disclosed in general for all nucleic acids (SEQ ID Nos. 1 to 304905) are not specific and are generally applicable to any nucleic acid."[3] Final Action at page 4.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51

---

[3] Applicants note that all sequences are the subject of applicants' invention and that the claims are restricted to SEQ ID NO: 2 because of the Examiner's restriction requirement.

U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecule provides identifiable benefits, for example use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. Either of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and they have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicants have asserted that the claimed nucleic acid molecule is itself useful for a utility disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms. Specification at page 47, line 20 though page 48, line 6. The specification also discloses additional utilities for the claimed nucleic acid molecule, including monitoring gene expression or for genetic mapping. Specification at page 54, lines 20-27 and page 55, lines 14-22. For example, a nucleic acid molecule can be used as a hybridization probe for identifying regions of identity-by-descent between two related individuals. Specification at page 56, lines 9-12. It is standard practice to screen populations of nucleic acid molecules with probes, often attached to a

microarray, without characterizing each and every target sequence. Mapping differences and/or similarities between two populations is in itself useful. For example, such information is useful to map desirable multigenic traits, such as disease resistance or enhanced yield. This is use of the claimed nucleic acid molecule in a real world context.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecule to identify the presence or absence of a polymorphism. Specification at page 47, line 20 through page 48, line 6 and at page 54, lines 10-12. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, *see* Final Action at page 4, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

Many of the disclosed utilities in this case, including this utility, are directly analogous to the utilities of a specialized screening assay, *i.e.*, the claimed nucleic acid molecule may be used to locate and measure nucleic acid molecules having specific characteristics within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are "non-specific" because they "are applicable to nucleic acids in general and not particular or specific to the nucleic acid of SEQ ID No. 2". *See* Final Action at pages 4-5. The Examiner, however, in doing so ignores the fact that SEQ ID No. 2 has a specific use due to its unique and particular nucleic acid sequence which is at once distinct and separate from all other non-identical nucleic acid sequences. This nucleic acid sequence can be used as a novel research tool which is specific for one type of molecule or characteristic. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-25.

Use of the claimed nucleic acid molecule to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the

chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[4] Likewise, the claimed nucleic acid molecule has utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecule has been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acid molecule, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules

Other uses for the claimed nucleic acid molecule are as a probe for other molecules for genetic mapping and monitoring of gene expression. Specification at page 41, line 25-26 and at page 54, lines 20-27. The Examiner suggests that these uses are not legal utilities because the specification has not disclosed any specific nucleic acid molecule that can be identified using the claimed nucleic acid molecule. Final Action at pages 4-5. This is not correct. The specification discloses that the claimed nucleic acid molecule can be used as a gene-specific hybridization target for measuring the expression of the corresponding plant gene.[5] Specification at page 54,

---

[4] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

[5] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

lines 20-27. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and so has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a use for such probes for monitoring gene expression is as a research tool for identifying novel gene expression patterns. Novel gene expression patterns can be used to identify novel genes and their corresponding promoters having desirable characteristics. Despite the Examiner's assertion that the Applicant "...fails to indicate how this would be done and what information it would provide..." one skilled in the art of gene expression readily appreciates the utility of a research tool for measuring the expression patterns of novel genes even when the sequences of such novel genes are unknown. Final Action at page 6.

One illustrative example of a use for such probes for genetic mapping is as a marker. Even if the function of the sequence is not defined, the location of the marker on a chromosome is valuable. In fact, many of the SNP markers currently in the public domain do not have an assigned function at this time, and yet are still recognized as valuable for plant breeding.[6] Such markers may be used to define the boundaries of a desired trait and to follow that trait through successive generations of plants.

In short, the Final Action appears to be arguing that the utility is not a legal utility simply because other molecules can be used for the same purpose, *i.e.*, as probes. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991)

---

[6] For example, many of the SNPs currently available through the SNP database ("dbSNP") provided by the National Center for Biotechnology Information (NCBI) are designated as "not within the gene locus for any annotated gene", "not within a transcript region for any annotated gene", and/or "not within a coding region for any annotated gene".

("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for hybridization to identify novel gene expression patterns or marker location. Identification of such an expression pattern would be desirable and particularly useful because it allows for isolation of a promoter having a specific expression pattern. Such promoter would itself allow for the expression of proteins at that specific temporal, spatial, or developmental state. Because the claimed nucleic acid molecule was isolated from soy, it provides an appropriate starting point for isolating a promoter active in soy plants. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecule, it would not obviate the utility of the claimed nucleic acid molecule. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecule could not be so used. Accordingly, the assertion of this utility as a probe for other molecules satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

It appears that the Final Action is arguing that the disclosed uses are legally insufficient or "insubstantial" under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[7]

There can be no question that one skilled in the art can use the claimed nucleic acid molecule in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, for example, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such a nucleic acid molecule. The utility of genomic sequences is not merely an academic issue; the real world value of genomic sequences is self-evident from the growth of both public efforts and private companies in the United States premised on the usefulness of genomic sequences.

---

[7] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

The market participants for genomic sequence products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of genomic sequences is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 706.03(a)(1). Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[8] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1).

---

[8] Examples of incredible utilities are given in MPEP § 2107 at page 2100-26, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

Applicants have explicitly identified specific and substantial utilities. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecule would not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

D. The Claimed Nucleic Acids Are Enable By The Specification

The enablement of the claimed nucleic acid molecule has been challenged. Claims 1-7 and 16-22 were erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecule allegedly lacks utility and therefore cannot be enabled. Final Action at page 6. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Date: 12/19/02

Lawrence M. Lavin, Jr.
(Registration No. 30,768)
MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis, MO 63167

APPENDIX A

1. A substantially purified nucleic acid molecule comprising a fragment from about 30 to about 300 nucleotides residues, wherein said fragment exhibits complete complementarity to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and a complement thereof.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a microsatellite sequence.

3. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.

4. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and a complement thereof.

5. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule further comprises a bacterial ORI site.

6. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule has a promoter or partial promoter region.

7. The substantially purified nucleic acid molecule according to claim 6, wherein said promoter region comprises a CAAT cis element and a TATA cis element and an additional cis element.

16. A substantially purified nucleic acid molecule consisting of a fragment from about 30 to about 300 nucleotides residues, wherein said fragment exhibits complete complementarity to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and a complement thereof.

17. The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule comprises a microsatellite sequence.

18. The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.

19. The substantially purified nucleic acid molecule according to claim 16, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 2 and a complement thereof.

20. The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule further comprises a bacterial ORI site.

21. The substantially purified nucleic acid molecule according to claim 19, wherein said nucleic acid molecule has a promoter or partial promoter region.

22. The substantially purified nucleic acid molecule according to claim 21, wherein said promoter region comprises a CAAT cis element and a TATA cis element and an additional cis element.